Remarks

I. Support for Amendments

Claim 35 has been amended to correct a minor typographical error. Therefore, the foregoing amendments add no new matter, and their entry and consideration are respectfully requested.

II. Status of the Claims

By the foregoing amendments, claim 35 has been amended. These amendments add no new matter. Upon entry of the amendments, claims 15-38 are pending in the application, with claim 15 being the sole independent claim.

III. Summary of the Office Action

In the Office Action dated January 30, 2003, the Examiner has made three rejections of the claims. Applicants respectfully traverse these rejections, and request reconsideration and withdrawal thereof. In addition, Applicants offer the following remarks concerning each element of the Office Action.

IV. The Rejection under 35 U.S.C. § 112, First Paragraph

In the Office Action at pages 3-4, the Examiner has rejected claims 15-38 under 35 U.S.C. § 112, first paragraph, for alleged nonenablement. Applicants respectfully traverse this rejection.

The enablement requirement of 35 USC § 112, first paragraph, is satisfied if the claimed invention is enabled so that any person skilled in the art can make and use the

invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Applicants submit that the full scope of the claimed methods, compositions and products of manufacture could be practiced and made by those of ordinary skill in the art without undue experimentation.

In making this rejection, the Examiner contends that while the specification enables a tumor treatment, it does not enable a tumor vaccine for use in preventing the development of a cancer. *See* Paper No. 16 at page 3. Applicants respectfully disagree. The present specification provides substantial guidance that would enable one of ordinary skill to make and use the claimed tumor vaccines without the need for undue experimentation. For example, the specification discusses the use of the claimed tumor vaccines in prevention of cancer development in various locations (*see, e.g.*, Specification at page 14, lines 19-25; at page 15, line 30, to page 16, line 3; and at page 16, lines 32-33). The effectiveness of exemplary tumor vaccines such as those claimed is also demonstrated, for example, in Figures 2 and 3. Finally, the Examples in the present specification, particularly Example 2 (most particularly at pages 21-24), clearly show the effectiveness of a tumor vaccine falling within the scope of the present claims in protecting animals against the development of cancers. Applicants remind the Examiner that a description of animal testing is sufficient to enable claims to therapeutic compositions and methods of their use. *See In re Brana*, 51 F.3d 1560, 1567-68 (Fed. Cir. 1995) (holding that animal testing results are sufficient to establish whether one skilled in the art would believe that a pharmaceutical compound has an asserted clinical utility for the purposes of compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph). The present specification clearly describes methods for preparation and use of the claimed tumor vaccines. Under *Brana*, one of ordinary skill

would thus recognize that the animal testing assays described in the present specification would be acceptable to demonstrate that the claimed tumor vaccines would work to protect animals from developing cancers. Hence, the ordinarily skilled artisan would not have to resort to undue experimentation to make and use the claimed tumor vaccines.

As the Federal Circuit has held:

> [t]he purpose of [the enablement] provision is to assure that the inventor provides sufficient information about the claimed invention that a person of skill in the field of the invention can make and use it without undue experimentation, relying on the patent specification and knowledge in the art.

Scripps Clinic & Research Foundation v. Genentech, Inc., 18 USPQ2d 1001, 1006 (Fed. Cir. 1991). Therefore, the Examiner is respectfully reminded that the proper standard of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the application, coupled with information known in the art, without undue experimentation. *United States v. Telectronics, Inc.*, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), citing *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 107 S. Ct. 1606 (1987). It is requested that in reconsidering this rejection, the Examiner also keep in mind that the question of undue experimentation is a matter of degree, and "the key word is 'undue,' not 'experimentation.'" *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), quoting *In re Angstadt*, 190 USPQ 214, 219 (C.C.P.A. 1976). The fact that *some* experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation must not be unduly extensive. *PPG Indus., Inc. v. Guardian Indus. Corp.*, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996), citing *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 224 USPQ 409, 413 (Fed. Cir. 1984). Indeed, practitioners in pharmaceutical and vaccine arts routinely

undertake such screening and optimization experimentation without considering it undue. *See, e.g., Wands*, 8 USPQ2d at 1406. Furthermore, the test of whether an amount of experimentation is undue is not merely quantitative; a considerable amount of experimentation is permissible, if it is merely routine (*i.e.*, uses methods known to those of ordinary skill in the relevant arts), or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. *See PPG Indus.*, 37 USPQ2d at 1623, citing *Ex parte Jackson*, 217 USPQ 804, 807 (Bd. Pat. App. & Inter. 1982).

As discussed above, the present specification clearly describes methods for preparation and use of the claimed tumor vaccines. In fact, the present specification goes *beyond* what is required for enablement of a claimed invention, by disclosing working examples of the preparation and use of tumor vaccines (*see* Examples 2 and 3) which are not even required for enablement. *See In re Wright*, 27 USPQ2d 1510, 1561 (Fed. Cir. 1999) ("Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples."); *see also In re Long*, 151 USPQ 640, 642 (C.C.P.A. 1966) ("absence of a working example does not in and of itself compel the conclusion that a specification does not satisfy the requirements of section 112."). Hence the present specification provides more than enough disclosure to meet the enablement requirement under 35 U.S.C. § 112, first paragraph, for the presently claimed invention.

In attempting to support the present rejection, the Examiner cites Evans *et al.*, *Q.J. Med. 92*:299-307 (1999) (hereinafter "Evans"), as an indication that the claimed invention

would have been unpredictable. *See* Paper No. 16, at page 4. However, the Examiner has taken a statement from Evans out of context and has disingenuously presented the statement in the Office Action in a context in which it was not intended by Evans. In the rejection, the Examiner states that:

> Evans *et al* teach that the use of tumor vaccines is far from being fully understood, and that the use of such vaccines in cancer treatment "still belongs to the realm of fiction."

Paper No. 16 at page 4, lines 15-16. In fact, this is *not* what Evans *et al.* have stated. The full quotation from Evans *et al.* is as follows:

> The notion that cancer vaccines will replace standard therapeutic strategies in malignant disease still belongs to the realms of fiction.

Evans at page 303, col. 2, lines 13-16. Hence, contrary to the Examiner's position, Evans does *not* say that the use of tumor vaccines in cancer treatment "still belongs to the realm[s] of fiction." Instead, the point being made in the full statement in Evans is that tumor vaccines may not yet be suitable for use *instead of* standard therapeutic strategies in malignant disease. Indeed, Evans provides significant discussion and citation of literature showing that tumor vaccines work to provide protection against a variety of cancers. *See, e.g.*, Evans at pages 301-303. Thus, Evans does *not* support the point for which the Examiner is using this reference in the present enablement rejection, and instead provides support that the production and use of tumor vaccines is, indeed, enabled.

Moreover, the question of why the present approaches to making and using tumor vaccines worked, while previous attempts to make and use tumor vaccines (some using different approaches) have failed (as the Examiner appears to contend is supported by Evans), is irrelevant to the patentability of the presently claimed invention. It is not

necessary for an applicant to understand, predict, speculate upon, or demonstrate how or why a claimed invention works when others have failed, since in order for a claimed method, composition or article of manufacture to be patentable, "an inventor is not required to understand how or why [the] invention works . . . ." *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); *see also Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989) ("[i]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works"), *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570 (Fed. Cir. 1983) ("[i]t is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests"). Therefore, the question of why the tumor vaccines made and used by the present invention work when others have failed is irrelevant to the patentability of the pending claims; since no mechanism appears in the claims, Applicants' demonstration (or putative lack thereof) of an understanding of how and why the process works in view of failure by others cannot be the basis for any rejection of the claims.

In view of the foregoing remarks, Applicants respectfully assert that the present specification fully enables the claimed invention. Reconsideration and withdrawal of the rejection therefore are respectfully requested.

V. The Rejection Under 35 U.S.C. § 102(b)

In the Office Action at pages 5-6, the Examiner has rejected claims 15-17, 22 and 24-30 under 35 U.S.C. § 102(b) as being anticipated by Golumbek *et al.*, *Cancer Res.* *53*:5841-5844 (1993) (Doc. No. AT5, of record; hereinafter "Golumbek"). Applicants respectfully traverse this rejection.

Under 35 U.S.C. § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). In addition, a claim can only be anticipated by a publication if the publication describes the claimed invention with sufficient enabling detail to place the public in possession of the invention. *See In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985); *see also PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter."). These requirements are not met by the disclosure of Golumbek, which does not disclose all of the elements of the present claims.

Perhaps recognizing that Golumbek fails to expressly disclose the presently claimed invention, the Examiner instead appears to contend that Golumbek *inherently* discloses the invention. *See* Paper No. 16 at page 6. Applicants respectfully disagree with this contention, and wish to remind the Examiner that "[i]n order for a disclosure to be inherent . . . the missing descriptive matter must necessarily be present in the [cited reference] such that one skilled in the art would recognize such a disclosure." *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998). Moreover, to rely on an inherency argument, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (PTO Bd. Pat. App. Int. 1990) (emphasis in original). That is, inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result

from a given set of circumstances is not sufficient." *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991). These standards are not met by the disclosure of Golumbek. Hence, the Examiner's attempted reliance upon inherent anticipation in the present case is factually and legally unfounded.

Accordingly, Applicants respectfully assert that Golumbek does not expressly or inherently disclose the claimed invention. Reconsideration and withdrawal of the rejection of claims 15-17, 22 and 24-30 under 35 U.S.C. § 102(b) therefore are respectfully requested.

VI. Rejection under 35 U.S.C. § 103

In the Office Action at pages 6-8, the Examiner has rejected claims 15-20, 22-26 and 28-38 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Golumbek in view of Porgador *et al.*, *J. Immunol. 150*:1458-1470 (1993) (Doc. No. AS10, of record; hereinafter "Porgador"). Applicants respectfully traverse this rejection.

In proceedings before the Patent and Trademark Office, the examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *See In re Piasecki*, 223 USPQ 785, 787-88 (Fed. Cir. 1984). The Examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references in such a way as to produce the invention as claimed. *See In re Fine*, 5 USPQ2d 1596,1598 (Fed. Cir. 1988). There is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time the invention was made. *See Fromson*

v. Advance Offset Plate, Inc., 755 F.2d 1549, 1556 (Fed. Cir. 1995). Instead, what is needed is a reason, suggestion, or motivation in the prior art that would motivate one of ordinary skill to combine the cited references, and that would also suggest a reasonable likelihood of success in making or using the claimed invention as a result of that combination. *See In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). In the present case, this burden has not been satisfied.

Applicants reiterate and incorporate herein the remarks made above concerning the disclosure of Golumbek. This reference does not disclose, suggest, or otherwise contemplate the invention as claimed. Hence, Golumbek is seriously deficient as a primary reference in the attempt to make out a *prima facie* case of obviousness. These deficiencies of Golumbek are not cured by the disclosure of Porgador. Thus, there is no disclosure or suggestion that would have motivated one of ordinary skill in the art to have combined the disclosures of Golumbek and Porgador in the attempt to make and use the claimed invention. Absent such disclosure, suggestion and motivation, the references cannot properly be combined in the attempt to make out a *prima facie* case of obviousness. *See Fine*, 5 USPQ2d at,1598; *see also Dow Chem. Co.*, 837 F.2d at 473.

Because Golumbek and Porgador do not disclose, suggest, or otherwise contemplate the presently claimed tumor vaccines, these references, alone or in combination, do not disclose or suggest all of the elements of the present claims. As such, under *Piasecki*, *Fromson*, *Fine* and *Dow Chemical*, a *prima facie* case of obviousness has not been established. Therefore, Applicants respectfully request that the rejection of claims 15-20, 22-26 and 28-38 under 35 USC § 103(a) be reconsidered and withdrawn.

VII. Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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